

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RAVGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 20-1730 (RGA) (JLH)
)	
MYRIAD GENETICS, INC. and)	
MYRIAD WOMEN'S HEALTH, INC.,)	
)	
Defendants.)	

**MYRIAD GENETICS, INC. AND MYRIAD WOMEN'S HEALTH, INC.'S
ANSWER AND AFFIRMATIVE DEFENSES**

Myriad Genetics, Inc. and Myriad Women's Health, Inc. (collectively, "Myriad") respectfully submit the following Answer and Affirmative Defenses in response to the Complaint of plaintiff Ravgen, Inc.

ANSWER

Myriad answers the allegations in the numbered paragraphs of the Complaint as follows:

1. Myriad admits that the Complaint purports to assert a claim for alleged patent infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Myriad denies, however, that there is any factual or legal basis for any such claim. Myriad further denies the remaining allegations of Complaint Paragraph 1.

2. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 2, and on that basis denies them.

3. Myriad Genetics, Inc. admits that it is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 320 Wakara Way, Salt Lake City, Utah 84108. Myriad Genetics, Inc. admits that it has appointed The Corporation Trust

Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801 as its agent for service of process.

4. Myriad Women's Health, Inc. admits that it is a company organized and existing under the laws of the State of Delaware, with a place of business at 180 Kimball Way, South San Francisco, California 94080. Myriad Women's Health, Inc. admits that it has appointed The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801 as its agent for service of process. Myriad Women's Health, Inc. admits that it is a wholly owned subsidiary of Myriad Genetics, Inc.

5. Myriad admits that it is a pioneering molecular diagnostics and genomics company, that it makes, uses, and sells various screening products, including the Myriad Prequel Prenatal Screen, and that the Myriad Prequel Prenatal Screen, previously marketed as the Prelude Prenatal Screen, is a noninvasive prenatal screen that uses cell-free DNA (cfDNA) to determine if a pregnancy is at an increased risk for chromosome abnormalities, such as Down syndrome. Myriad denies the remaining allegations of Complaint Paragraph 5.

6. Myriad admits that it has offered and marketed the Prequel Prenatal Screen, previously marketed as the Prelude Prenatal Screen, and the Informed Pregnancy Screen, throughout the United States, including through the website www.myriadwomenshealth.com. Myriad denies the remaining allegations of Complaint Paragraph 6.

7. Myriad realleges and reincorporates herein by reference its responses to Plaintiff's allegations in Complaint Paragraphs 1 through 6.

8. Myriad admits that the Complaint purports to assert a claim for alleged patent infringement and that the Court has subject matter jurisdiction over such a claim pursuant to

28 U.S.C. §§ 1331 and 1338(a). Myriad denies, however, that there is any factual or legal basis for any such claim and further denies any other allegations contained in Complaint Paragraph 8.

9. Myriad Genetics, Inc. and Myriad Women's Health, Inc. admit that they are organized under the laws of Delaware. For purposes of this civil action only, Myriad consents to venue in this District. Myriad otherwise denies the allegations contained in Complaint Paragraph 9.

10. Myriad admits that it offers products and services through its websites. For purposes of this civil action only, Myriad consents to personal jurisdiction in this District. Myriad otherwise denies the allegations contained in Complaint Paragraph 10.

11. Myriad Genetics, Inc. and Myriad Women's Health, Inc. admit that they are organized under the laws of Delaware. For purposes of this civil action only, Myriad consents to personal jurisdiction in this District. Myriad otherwise denies the allegations contained in Complaint Paragraph 11.

BACKGROUND OF THE ALLEGED INVENTION

12. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 12, and on that basis denies them.

13. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 13, and on that basis denies them.

14. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 14, and on that basis denies them.

15. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 15, and on that basis denies them.

16. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 16, and on that basis denies them.

17. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 17, and on that basis denies them.

18. Myriad admits that Exhibit 13 appears to be an article that states, “the methods described herein for increasing the percentage of free fetal DNA provide a solid foundation for the development of a noninvasive prenatal diagnostic test.” Myriad denies that Exhibit 13 states, “the methods described herein for increasing the percentage of cell-free fetal DNA provide a solid foundation for the development of a noninvasive prenatal diagnostic test.” Myriad lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 18, and on that basis denies them.

19. Myriad admits that Complaint Paragraph 19 reproduces two excerpts from Exhibit 14. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 19, and on that basis denies them.

20. Myriad admits that the cited articles were published in 2007. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 20, and on that basis denies them.

21. Myriad admits that the cited articles were published in 2007. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 21, and on that basis denies them.

22. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 22, and on that basis denies them.

PATENTS-IN-SUIT

23. Myriad realleges and reincorporates herein by reference its responses to Plaintiff's allegations in Complaint Paragraphs 1 through 22.

24. Myriad admits that what appears to be a copy of U.S. Patent No. 7,332,277 ("the '277 patent") was attached to the Complaint as Exhibit 1. Myriad admits that, on its face, the '277 patent is titled "Methods For Detection Of Genetic Disorders" and lists February 19, 2008 as the date on which it issued. Myriad admits that, on its face, the '277 patent lists Ravinder S. Dhalla as the inventor and states that it is assigned to RavGen, Inc. Myriad denies the remaining allegations of Complaint Paragraph 24, and specifically denies that the '277 patent was duly and legally issued.

25. Myriad denies that there is any factual or legal basis for any claim of infringement of the '277 patent or any claim to damages for any such alleged infringement. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 25, and on that basis denies them.

26. Myriad admits that what appears to be a copy of U.S. Patent No. 7,727,720 ("the '720 patent") was attached to the Complaint as Exhibit 1. Myriad admits that, on its face, the '720 patent is titled "Methods For Detection Of Genetic Disorders" and lists June 1, 2010 as the date on which it issued. Myriad admits that, on its face, the '720 patent lists Ravinder S. Dhalla as the inventor and states that it is assigned to Ravgen, Inc. Myriad denies the remaining allegations of Complaint Paragraph 26, and specifically denies that the '720 patent was duly and legally issued.

27. Myriad denies that there is any factual or legal basis for any claim of infringement of the '720 patent or any claim to damages for any such alleged infringement. Myriad lacks

knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Complaint Paragraph 27 and on that basis denies them.

28. Myriad refers to Exhibit 1 of the Complaint for the content of the '277 patent. Myriad denies the remaining allegations of Complaint Paragraph 28 and specifically denies that claim 81 of the '277 patent was duly and legally issued.

29. Myriad refers to Exhibit 2 of the Complaint for the content of the '720 patent. Myriad denies the remaining allegations of Complaint Paragraph 29 and specifically denies that claim 1 of the '720 patent was duly and legally issued.

30. Myriad refers to Exhibit 1 of the Complaint for the content of the '277 patent and to Exhibit 2 of the Complaint for the content of the '720 patent. Myriad denies the remaining allegations of Complaint Paragraph 30.

31. Myriad refers to Exhibit 1 of the Complaint for the content of the '277 patent and to Exhibit 2 of the Complaint for the content of the '720 patent. Myriad denies the remaining allegations of Complaint Paragraph 31.

32. Myriad states that the cited exhibit speaks for itself. Myriad denies the remaining allegations of Complaint Paragraph 32.

33. Myriad states that the cited exhibit speaks for itself. Myriad denies the remaining allegations of Complaint Paragraph 33.

34. Myriad refers to Exhibit 1 of the Complaint for the content of the '277 patent and states that the cited exhibit speaks for itself. Myriad denies the remaining allegations of Complaint Paragraph 34 and specifically denies that claim 1 of the '277 patent was duly and legally issued.

35. Myriad refers to Exhibit 1 of the Complaint for the content of the '277 patent. Myriad admits that the '277 patent distinguishes the claimed methods from methods that sequence

regions beyond the desired bases or loci. Myriad denies the remaining allegations of Complaint Paragraph 35.

36. Myriad states that the cited exhibit speaks for itself. Myriad denies the remaining allegations of Complaint Paragraph 36.

MYRIAD'S ALLEGED INFRINGING ACTIVITIES

37. Myriad realleges and reincorporates herein by reference its responses to Plaintiff's allegations in Complaint Paragraphs 1 through 36.

A. The Accused Myriad Prenatal Screen

38. Myriad admits that in or around September 2014, Counsyl, Inc. began offering the Informed Pregnancy Screen, a commercial non-invasive prenatal screen for detecting fetal chromosomal abnormalities. Myriad denies the remaining allegations of Complaint Paragraph 38.

39. Myriad admits that it acquired Counsyl through a merger transaction and renamed it to Myriad Women's Health. Myriad admits that subsequent to this transaction, the Prelude Prenatal Screen was renamed the Prequel Prenatal Screen. Myriad denies the remaining allegations of Complaint Paragraph 39.

40. Myriad admits the allegations of Complaint Paragraph 40.

41. Myriad denies the allegations of Complaint Paragraph 41.

42. Myriad admits that the Prequel Prenatal Screen is a noninvasive prenatal screen that uses cell-free DNA (cfDNA) to determine if a pregnancy is at an increased risk for common chromosome abnormalities, such as Down syndrome. Myriad further admits that the Prequel Prenatal Screen can be performed with a sample of maternal blood. Myriad denies the remaining allegations of Complaint Paragraph 42.

43. Myriad admits that it currently includes a Streck Cell-Free DNA BCT® in the Prequel Prenatal Screen sample collection kit. Myriad states that the cited exhibits speak for themselves. Myriad denies the remaining allegations of Complaint Paragraph 43.

44. Myriad lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Complaint Paragraph 44 and on that basis denies them. Myriad refers to the cited Exhibits of Complaint Paragraph 44 for the content of those exhibits.

45. Myriad admits that the Prequel Prenatal Screen utilizes a whole genome sequencing (WGS) approach. Myriad states that the cited exhibits speak for themselves. Myriad denies the remaining allegations of Complaint Paragraph 45.

B. Myriad's Alleged Knowledge Of The Ravgen Patents

46. Myriad admits that it actively participates in the genetic testing industry. Myriad denies the remaining allegations of Complaint Paragraph 46.

47. Myriad denies that it has infringed the Patents-in-Suit and denies that it was willfully blind to the Patents-in-Suit or any such alleged infringement. Myriad denies any remaining allegations of Complaint Paragraph 47.

48. Myriad denies that it has infringed the Patents-in-Suit and denies that it was willfully blind to the Patents-in-Suit or any such alleged infringement. Myriad denies any remaining allegations of Complaint Paragraph 48.

49. Myriad admits that the '277 patent was cited during prosecution and in the specification of U.S. Patent Application Publication No. 2010/0022406. Myriad denies that it has infringed the Patents-in-Suit and denies that it was willfully blind to the Patents-in-Suit or any such alleged infringement. Myriad denies the remaining allegations of Complaint Paragraph 49.

50. Myriad denies that it has infringed the Patents-in-Suit and denies that it was willfully blind to the Patents-in-Suit or any such alleged infringement. Myriad denies any remaining allegations of Complaint Paragraph 50.

51. Myriad denies the allegations of Complaint Paragraph 51.

COUNT I
(Alleged And Denied Direct Infringement Of The '277 Patent)

52. Myriad realleges and reincorporates herein by reference its responses to Plaintiff's allegations in Complaint Paragraphs 1 through 51.

53. Myriad denies the allegations of Complaint Paragraph 53.

54. Myriad denies the allegations of Complaint Paragraph 54.

55. Myriad denies the allegations of Complaint Paragraph 55.

56. Myriad denies the allegations of Complaint Paragraph 56.

57. Myriad denies the allegations of Complaint Paragraph 57.

58. Myriad denies the allegations of Complaint Paragraph 58.

59. Myriad denies the allegations of Complaint Paragraph 59.

60. Myriad denies the allegations of Complaint Paragraph 60.

61. Myriad denies the allegations of Complaint Paragraph 61.

62. Myriad denies the allegations of Complaint Paragraph 62.

63. Myriad denies the allegations of Complaint Paragraph 63.

COUNT II
(Alleged And Denied Direct Infringement Of The '720 Patent)

64. Myriad realleges and reincorporates herein by reference its responses to Plaintiff's allegations in Complaint Paragraphs 1 through 63.

65. Myriad denies the allegations of Complaint Paragraph 65.

66. Myriad denies the allegations of Complaint Paragraph 66.

- 67. Myriad denies the allegations of Complaint Paragraph 67.
- 68. Myriad denies the allegations of Complaint Paragraph 68.
- 69. Myriad denies the allegations of Complaint Paragraph 69.
- 70. Myriad denies the allegations of Complaint Paragraph 70.
- 71. Myriad denies the allegations of Complaint Paragraph 71.
- 72. Myriad denies the allegations of Complaint Paragraph 72.
- 73. Myriad denies the allegations of Complaint Paragraph 73.
- 74. Myriad denies the allegations of Complaint Paragraph 74.
- 75. Myriad denies the allegations of Complaint Paragraph 75.

PRAYER FOR RELIEF

Myriad denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief and asks that judgment be entered for Myriad on all of Plaintiff's claims, awarding Myriad its costs and fees and such other and further relief as the Court deems appropriate.

GENERAL DENIAL

To the extent not specifically admitted herein, the allegations of the Complaint are denied. Myriad denies any allegations that may be implied by or inferred from the headings of the Complaint.

AFFIRMATIVE DEFENSES

Myriad alleges and asserts the following defenses in response to the Complaint, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. In addition to the defenses described below, Myriad reserves all rights to allege additional defenses, affirmative or otherwise, that become known through the course of discovery.

First Affirmative Defense: Failure To State A Claim

Plaintiff has failed to state a claim upon which relief can be granted.

Second Affirmative Defense: No Infringement

Myriad has not infringed, and is not infringing, any valid claim of the '277 or '720 patent.

Third Affirmative Defense: Invalidity Under Part II Of Title 35

The claims of the '277 and '720 patents are invalid for failing to satisfy one or more of the requirements of Part II of Title 35 of the United States Code, including without limitation, 35 U.S.C. §§ 101, 102, 103 and 112.

Fourth Affirmative Defense: Statute of Limitations

Plaintiff's claims for damages are limited by 35 U.S.C. § 286.

Fifth Affirmative Defense: No Entitlement To An Injunction

Plaintiff's claims for injunctive relief are barred because, *inter alia*, Plaintiff has an adequate remedy at law, and an injunction would harm the public by depriving the public of potentially life-saving prenatal testing.

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February 11, 2021

CERTIFICATE OF SERVICE

I hereby certify that on February 11, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 11, 2021, upon the following in the manner indicated:

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